

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

PORAL INSTRUMENTS, INC.,

Case No.: 22 Civ. 9156 (JHR)

Plaintiff,

v.

LEO PHARMA A/S,

Defendant.

LEO PHARMA A/S'S ANSWER TO PLAINTIFF'S COMPLAINT

LEO Pharma A/S (“LEO”), by and through its undersigned counsel, files this Answer to the Complaint, filed by Plaintiff Portal Instruments, Inc. (“Portal,” and with LEO, the “Parties”). LEO denies all allegations not expressly admitted in this Answer, including allegations found in the Complaint’s headings and elsewhere.

RESPONSE TO STATEMENT OF THE CASE

1. LEO denies the allegations in the first sentence of Paragraph 1. LEO lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 1 and denies the allegations on that basis.

2. The allegations in Paragraph 2 relate to a claim that has been dismissed, consist of legal conclusions or argument, and therefore do not require a response. To the extent any response is required, LEO admits that it entered into the Collaboration and License Agreement (the “Agreement”) with Portal in December 2019 relating to the development of a drug delivery system for LEO’s products, and denies the remaining allegations in Paragraph 2.

3. LEO admits that the Agreement provided for certain milestone payments relating the achievement of milestones defined in the Agreement, respectfully refers to the Agreement for its complete contents, and denies the remaining allegations in Paragraph 3.

4. The allegations in Paragraph 4 consist of legal conclusions or argument and therefore do not require a response. To the extent any response is required, LEO admits that Portal's complaint purports to assert three counts against LEO, denies that Portal is entitled to any relief, and denies any remaining allegations in Paragraph 4.

RESPONSE TO PARTIES

5. LEO admits, upon information and belief, that Portal is a corporation incorporated in Delaware with its principal place of business in Cambridge, Massachusetts. LEO lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 5 and denies the allegations on that basis.

6. LEO admits the allegations in Paragraph 6.

RESPONSE TO JURISDICTION AND VENUE

7. The allegations in Paragraph 7 are legal conclusions to which no response is required. To the extent a response is deemed necessary, LEO does not contest that this Court has subject matter jurisdiction.

8. The allegations in Paragraph 8 are legal conclusions to which no response is required. To the extent a response is deemed necessary, LEO does not contest that it is subject to personal jurisdiction in this Court.

9. The allegations in Paragraph 9 are legal conclusions to which no response is required. To the extent a response is deemed necessary, LEO does not contest that venue is proper.

RESPONSE TO FACTS

10. LEO admits that the Parties entered into the Agreement on December 3, 2019; that one of the purposes of the Agreement was to jointly develop certain drug delivery systems to be used with LEO's drugs; and that the Agreement provided for certain payments to Portal under conditions specified in the Agreement. LEO respectfully refers to the Agreement for its complete contents and denies any remaining allegations in Paragraph 10.

11. LEO admits that, under the Agreement, it could elect to develop with Portal the 1x2mL System, the 2x1mL System, or both the 1x2mL System and 2x1mL System. LEO respectfully refers to the Agreement for its complete contents and denies any remaining allegations in Paragraph 11.

12. LEO admits that Section 4.1 of the Agreement states in part that LEO and Portal "shall use Commercially Reasonable Efforts to collaborate in Developing the Project" LEO further admits that the Agreement allowed LEO to "at any point after making its election pursuant to this Section 4.2, in its sole discretion, provide Portal with written notification to change its election, including to cease and/or commence to Develop a System under the Development Plan." LEO respectfully refers to the Agreement for its complete contents, and denies any remaining allegations in Paragraph 12.

13. The allegations in Paragraph 13 relate to a claim that has been dismissed, and therefore do not require a response. To the extent any response is required, LEO admits that Section 7.2(a) provides for certain quarterly development fee payments if LEO elects to develop the 1x2mL System, denies any remaining allegations in Paragraph 13, and respectfully refers to the Agreement for its complete contents.

14. LEO admits that Section 17.2(a) of the Agreement granted LEO "the right to terminate the Agreement in its entirety, on a Product-by-Product basis, or on a county-by-country

[sic] basis at will upon ninety days' prior written notice" LEO respectfully refers to the Agreement for its complete contents, and denies any remaining allegations in Paragraph 14.

15. LEO admits that it elected to begin development of the 1x2mL System, as well as the 2x1mL System. LEO lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 15 and denies the allegations on that basis.

16. The allegations in Paragraph 16 relate to a claim that has been dismissed, consist of legal conclusions or argument, and therefore do not require a response. To the extent any response is required, LEO lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 16 and denies the allegations on that basis.

17. The allegations in Paragraph 17 relate to a claim that has been dismissed, and therefore do not require a response. To the extent any response is required, LEO denies the allegations in Paragraph 17 and respectfully refers the Court to the Agreement for the complete contents thereof.

18. The allegations in Paragraph 18 relate to a claim that has been dismissed, and therefore do not require a response.

19. LEO admits the allegations in Paragraph 19.

20. LEO admits that it provided Portal a written termination notice on September 15, 2021 informing Portal of LEO's decision to terminate the Agreement "with effect as of December 22, 2021," respectfully refers to the termination notice for its complete contents, and denies any remaining allegations in Paragraph 20.

21. The allegations in Paragraph 21 relate to a claim that has been dismissed, and therefore do not require a response. To the extent a response is necessary, LEO admits that the Termination Notice includes the quoted language.

22. The allegations in Paragraph 22 relate to a claim that has been dismissed, and therefore do not require a response. To the extent that any response is required, LEO admits that it informed Portal of its intent to terminate by phone prior to sending the written termination notice.

23. The allegations in Paragraph 23 relate to a claim that has been dismissed, and therefore do not require a response. To the extent that any response is required, LEO denies the allegations in Paragraph 23.

24. LEO admits that Section 17.2(a) of the Agreement granted LEO “the right to terminate the Agreement in its entirety, on a Product-by-Product basis, or on a county-by-country [sic] basis at will upon ninety days’ prior written notice” LEO respectfully refers to the Agreement for its complete contents, and denies any remaining allegations in Paragraph 24.

25. The allegations in Paragraph 25 consist of legal conclusions or argument, and therefore do not require a response.

26. The allegations in Paragraph 26 relate to a claim that has been dismissed, consist of legal conclusions or argument, and therefore do not require a response. To the extent any response is required, LEO denies the allegations in Paragraph 26.

27. The allegations in Paragraph 27 relate to a claim that has been dismissed, and therefore do not require a response. To the extent any response is required, LEO denies that the referenced Development Fee payment was “due,” admits that the payment was not made, and further avers that the payment was not required.

28. The allegations in Paragraph 28 relate to a claim that has been dismissed, consist of legal conclusions or argument, and therefore do not require a response. To the extent any response is required, LEO denies the allegations in Paragraph 28.

29. The allegations in Paragraph 29 relate to a claim that has been dismissed, and therefore do not require a response.

30. The allegations in Paragraph 30 relate to a claim that has been dismissed, and therefore do not require a response. To the extent any response is required, LEO admits that the Agreement contains the quoted language.

31. The allegations in Paragraph 31 relate to a claim that has been dismissed, consist of legal conclusions or argument, and therefore do not require a response. To the extent any response is required, LEO denies the allegations in Paragraph 31.

32. The allegations in Paragraph 32 consist of legal conclusions or argument to which no response is required. To the extent any response is required, LEO admits the allegations of Paragraph 32.

33. The allegations in Paragraph 33 relate to a claim that has been dismissed, consist of legal conclusions or argument, and therefore do not require a response. To the extent any response is required, LEO denies the allegations in Paragraph 33.

34. The allegations in Paragraph 34 relate to a claim that has been dismissed, consist of legal conclusions or argument, and therefore do not require a response. To the extent any response is required, LEO denies the allegations in Paragraph 34.

35. The allegations in Paragraph 35 relate to a claim that has been dismissed, consist of legal conclusions or argument, and therefore do not require a response. To the extent any response is required, LEO denies the allegations in Paragraph 35.

36. The allegations in Paragraph 36 relate to a claim that has been dismissed, consist of legal conclusions or argument, and therefore do not require a response. To the extent any response is required, LEO denies the allegations in Paragraph 36.

37. The allegations in Paragraph 37 relate to a claim that has been dismissed, and therefore do not require a response. To the extent a response is deemed necessary, LEO admits that it has not paid Portal the 8th Quarterly payment and further avers that no such payment is required under the Agreement.

38. LEO admits that the Agreement provided for certain milestone payments relating to the achievement of milestones defined in the Agreement, denies that it committed any breaches of the Agreement and any remaining allegations in Paragraph 38, and respectfully refers to the Agreement for its complete contents.

39. LEO admits that Section 7.3 of the Agreement includes the quoted text and a table of milestones and their associated payment amounts, denies that it was obligated to make any of the milestone payments, and respectfully refers to the Agreement for its complete contents.

40. LEO admits that Section 7.3 of the Agreement includes the quoted text, denies that it was obligated to make any milestone payments and any remaining allegations in Paragraph 40, and respectfully refers to the Agreement for its complete contents.

41. LEO admits that Section 4.1 contains the quoted text and respectfully refers to the Agreement for its complete contents.

42. LEO denies the allegations in Paragraph 42.

43. LEO denies the allegations in Paragraph 43.

44. LEO denies the allegations in Paragraph 44.

45. LEO denies the allegations in Paragraph 45.

46. LEO denies the allegations in Paragraph 46.

47. LEO lacks knowledge and information sufficient to form a belief as to the truth of the allegations in the first sentence of Paragraph 47, and denies the allegations on that basis. LEO denies the remaining allegations in Paragraph 47.

48. LEO admits that a Pharmacokinetics Phase Report for Study No. 288707 sent to Portal includes the quoted text, and respectfully refers to that Report for its complete contents.

49. LEO admits that a Pharmacokinetics Phase Report for Study No. 288707 sent to Portal includes the quoted text, and respectfully refers to that Report for its complete contents.

50. LEO denies the allegations in Paragraph 50.

51. LEO admits that it did not make a \$1 million milestone payment to Portal, denies that it had any obligation to make such a payment, denies that it breached the Agreement, and denies all remaining allegations in Paragraph 51.

52. LEO denies the allegations in Paragraph 52.

53. LEO denies the allegations in Paragraph 53.

54. LEO denies the allegations in Paragraph 54.

55. LEO denies the allegations in Paragraph 55.

56. LEO denies the allegations in Paragraph 56.

57. LEO denies the allegations in Paragraph 57.

58. LEO denies the allegations in Paragraph 58.

59. LEO denies the allegations in Paragraph 59.

60. LEO denies the allegations in Paragraph 60.

61. LEO admits that it has not made the milestone payment to Portal, and denies that it had any obligation to do so.

RESPONSE TO FIRST CAUSE OF ACTION

62. LEO incorporates by reference all of its responses to the preceding paragraphs of the Complaint, including without limitation all denials therein, as if fully set forth below.

63. The allegations in Paragraph 63 consist of legal conclusions or argument and therefore do not require a response.

64. The allegations in Paragraph 64 relate to a claim that has been dismissed, consist of legal conclusions or argument, and therefore do not require a response. To the extent any response is required, LEO denies the allegations in Paragraph 64.

65. The allegations in Paragraph 65 relate to a claim that has been dismissed, consist of legal conclusions or argument, and therefore do not require a response. To the extent any response is required, LEO denies the allegations in Paragraph 65.

66. The allegations in Paragraph 66 relate to a claim that has been dismissed, consist of legal conclusions or argument, and therefore do not require a response. To the extent any response is required, LEO denies the allegations in Paragraph 66.

67. The allegations in Paragraph 67 relate to a claim that has been dismissed, consist of legal conclusions or argument, and therefore do not require a response. To the extent any response is required, LEO denies the allegations in Paragraph 67.

RESPONSE TO SECOND CAUSE OF ACTION

68. LEO incorporates by reference all of its responses to the preceding paragraphs of the Complaint, including without limitation all denials therein, as if fully set forth below.

69. The allegations in Paragraph 69 consist of legal conclusions or argument and therefore do not require a response.

70. The allegations in Paragraph 70 consist of legal conclusions or argument and therefore do not require a response. To the extent any response is required, LEO denies that it was obligated

to make the milestone payment, and respectfully refers to Section 7.3 of the Agreement for its complete contents.

71. LEO denies the allegations in Paragraph 71.

72. The allegations in Paragraph 72 consist of legal conclusions or argument and therefore do not require a response. To the extent any response is required, LEO denies the allegations in Paragraph 72.

73. The allegations in Paragraph 73 consist of legal conclusions or argument and therefore do not require a response. To the extent any response is required, LEO denies the allegations in Paragraph 73.

RESPONSE TO THIRD CAUSE OF ACTION

74. LEO incorporates by reference all of its responses to the preceding paragraphs of the Complaint, including without limitation all denials therein, as if fully set forth below.

75. The allegations in Paragraph 75 consist of legal conclusions or argument and therefore do not require a response.

76. The allegations in Paragraph 76 relate to a claim that has been dismissed or abandoned, consist of legal conclusions or argument, and therefore do not require a response. To the extent any response is required, LEO denies the allegations in Paragraph 76.

77. The allegations in Paragraph 77 relate to a claim that has been dismissed or abandoned, and therefore do not require a response. To the extent any response is required, LEO denies the allegations in Paragraph 77.

78. The allegations in Paragraph 78 relate to a claim that has been dismissed or abandoned, consist of legal conclusions or argument, and therefore do not require a response. To the extent any response is required, LEO denies the allegations in Paragraph 78.

79. The allegations in Paragraph 79 consist of legal conclusions or argument, and therefore do not require a response. To the extent any response is required, LEO denies the allegations in Paragraph 79.

80. The allegations in Paragraph 80 consist of legal conclusions or argument, and therefore do not require a response. To the extent any response is required, LEO denies the allegations in Paragraph 80.

81. The allegations in Paragraph 81 consist of legal conclusions or argument, and therefore do not require a response. To the extent any response is required, LEO denies the allegations in Paragraph 81.

82. The allegations in Paragraph 82 consist of legal conclusions or argument, and therefore do not require a response. To the extent any response is required, LEO denies the allegations in Paragraph 82.

RESPONSE TO PRAYER FOR RELIEF

The allegations in the unnumbered paragraph following Paragraph 82 of the Complaint contains Portal's prayer for relief, to which no response is required. To the extent a response is required, LEO denies that Portal is entitled to the relief requested or to any other relief.

RESPONSE TO JURY DEMAND

LEO denies that Portal is entitled to a trial by jury. LEO further states that Portal waived any right to a jury trial in Section 19.11(d) of the Parties' Agreement, which provides:

Waiver of Jury Trial. EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY WAIVES ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATED TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY.

AFFIRMATIVE AND OTHER DEFENSES

Without assuming any burden that it would not otherwise have, LEO asserts the defenses set forth below. By virtue of alleging these further defenses, LEO does not assume any burden of proof, persuasion, or production not otherwise legally assigned to it. LEO also does not concede that facts contrary to one or more of the averments that follow would support liability as to it. LEO reserves all rights to assert additional or amended defenses.

FIRST DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

SECOND DEFENSE

Portal's claims are barred, in whole or in part, due to the failure of a condition precedent, including the lack of achievement of the Milestone Event.

THIRD DEFENSE

Portal's claims are barred, in whole or in part, by the doctrines of waiver, estoppel, ratification, acquiescence, condonation, laches, and/or other equitable doctrines.

FOURTH DEFENSE

Portal's claims are barred, in whole or in part, because Portal has not suffered any actual injury or damages caused by LEO.

FIFTH DEFENSE

Portal's claims are barred, in whole or in part, by the terms of the Agreement.

SIXTH DEFENSE

Portal's claims are barred, in whole or in part, because Portal seeks to impose obligations on LEO that go beyond the obligations set forth in the Agreement or that may exist by law.

SEVENTH DEFENSE

Portal's claims are barred, in whole or in part, because Portal's alleged injury and damages, if any, were the result of intervening or superseding events, factors, occurrences, or conditions that were not caused by LEO and for which LEO is not responsible.

EIGHTH DEFENSE

Portal's claims are barred, in whole or in part, because LEO acted in good faith and not irrationally or arbitrarily.

NINTH DEFENSE

Portal's claim for breach of the implied covenant of good faith and fair dealing is barred, in whole or in part, because the claim is duplicative of Portal's breach of contract claims and/or seeks to impose obligations different from or beyond those imposed by the Parties' Agreement.

TENTH DEFENSE

Portal is not entitled to recover any attorneys' fees, costs, disbursements, interests, or costs.

Dated: December 6, 2023

Respectfully submitted,

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